# EXHIBIT A

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

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No. 16-11818

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D.C. Docket Nos. 1:14-cv-24061-JRG,
1:14-cv-24064-JRG

1:14-cv-24061-JRG

AMAL EGHNAYEM,
MARGARITA M. DOTRES,
MANIA NUNEZ,
JUANA BETANCOURT,

Plaintiffs - Appellees,

MARGARETTE DUBOIS-JEAN,

Plaintiff,

versus

BOSTON SCIENTIFIC CORPORATION,

Defendant - Appellant.

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1:14-cv-24064-JRG Dismissed 02/23/2017

MARGARITA M. DOTRES,

Plaintiff,

versus

BOSTON SCIENTIFIC CORPORATION,

Defendant.

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1:14-cv-24065-JRG

MANIA NUNEZ,

Plaintiff - Appellee,

versus

BOSTON SCIENTIFIC CORPORATION,

Defendant - Appellant.

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1:14-cv-24066-JRG

JUANA BETANCOURT,

Plaintiff - Appellee,

versus

BOSTON SCIENTIFIC CORPORATION,

Defendant - Appellant.

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Appeal from the United States District Court
for the Southern District of Florida

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(October 19, 2017)

Before HULL, MARCUS, and ROGERS,* Circuit Judges.

MARCUS, Circuit Judge:

In this products liability suit, Boston Scientific Corporation (BSC) appeals from various orders and a final judgment in favor of the plaintiff, Amal Eghnayem. Eghnayem alleged substantial injuries caused by the Pinnacle Pelvic Floor Repair Kit, a transvaginal mesh prescription medical device manufactured and sold by BSC. She initially filed suit in the Southern District of West Virginia as part of a transvaginal mesh Multidistrict Litigation; her suit was consolidated with three other similar suits and transferred to the Southern District of Florida for trial. The consolidated plaintiffs all brought the same four claims under Florida law, arguing that BSC was both negligent and strictly liable for the Pinnacle's defective design, and both negligent and strictly liable for failing to warn them of the resultant danger from the Pinnacle. After eight days of trial, the jury found for each of the plaintiffs on all four claims, awarding more than six million dollars to each plaintiff. BSC now appeals from the judgment entered for

* Honorable John M. Rogers, United States Circuit Judge for the Sixth Circuit, sitting by designation.

Eghnayem.[1]

BSC argues that the district court abused its discretion in two distinct ways: by consolidating the four plaintiffs' suits and trying them together, and by excluding all evidence relating to the Food and Drug Administration's clearance of the Pinnacle for sale through its 510(k) "substantial equivalence" process. BSC also says that the district court erred in denying it judgment as a matter of law because Eghnayem failed to present sufficient evidence to prove her design defect claim; she failed to present sufficient evidence that the Pinnacle's warnings were not per se adequate, and that the alleged failure to warn was the proximate cause of her injuries; and finally, the relevant statute of limitations barred all of her claims as a matter of law.

After thorough review, and having had the benefit of oral argument, we can discern no error in the district court's rulings, and accordingly we affirm the judgment of the district court.

## I.

The Pinnacle is a medical device used to remedy pelvic organ

[1] BSC initially appealed from the judgment in favor of all four plaintiffs: Eghnayem, Margarita M. Dotres, Mania Nuñez, and Juana Betancourt. Prior to oral argument, BSC dismissed the appeal as to Dotres. BSC has since moved to dismiss the appeal as to co-plaintiffs Nuñez and Betancourt as well. That motion is GRANTED.

prolapse in a female patient. Essentially, this device is a mesh sheet that is implanted transvaginally and works by physically preventing pelvic organs (the bladder, uterus, or rectum) from falling through the vagina. The mesh is made from polypropylene, a type of plastic. In 2007, the FDA cleared BSC to sell the Pinnacle pursuant to its 510(k) process, which entailed finding that the Pinnacle was "substantially equivalent" to another device already available on the market.

The plaintiff, Amal Eghnayem, had a Pinnacle surgically implanted on February 28, 2008, to treat her pelvic organ prolapse. In the months following her surgery, she began to experience bleeding and pain during intercourse, incontinence, and pelvic pain and pressure. She visited a doctor for these problems in October 2008, who performed a pelvic exam and told Eghnayem that she had exposed mesh in her vagina. The doctor performed in-office surgery to trim the exposed mesh in an attempt to alleviate Eghnayem's symptoms. Unfortunately, this treatment did not resolve her problems, and in May 2012, she visited another doctor and complained of similar symptoms. This doctor examined Eghnayem, found another mesh exposure, and performed a second mesh-removal surgery in August 2012. Since then,

Eghnayem's pain has largely subsided, but she has lost vaginal sensitivity.

Eghnayem and three other plaintiffs filed separate lawsuits against BSC in MDL 2326 -- In re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation -- in the United States District Court for the Southern District of West Virginia. They each sought compensatory and punitive damages based on claims for negligent design defect, negligent failure to warn, strict-liability design defect, and strict-liability failure to warn. The district court sua sponte consolidated the suits for all purposes, including trial. The court observed that, although "there will be separate evidence relating to failure to warn and individual damages," "the similarities in these cases, particularly as to the claim of design defect," outweighed the differences and warranted consolidation.

BSC moved the district court to sever the suits after discovery, arguing that the similarities in the plaintiffs' suits did not predominate and that consolidation would lead to jury confusion and prejudice. It pointed out that each plaintiff had different complaints, different medical histories, and different treating doctors; was prescribed the

Pinnacle at different times for different conditions; and claimed to suffer different injuries, after different lengths of exposure, resulting in different treatment courses. But the district court was "unpersuaded that the barriers suggested by defendants in a consolidated trial [were] insurmountable or [would] result in [ ] prejudice" and so denied BSC's motion.

The consolidated case was transferred to the United States District Court for the Southern District of Florida. Prior to trial, the district court excluded all evidence relating to the Food and Drug Administration's ("FDA") regulatory scheme and clearance of the Pinnacle for sale pursuant to the 510(k) "substantial equivalence" process. The court excluded the evidence under both Federal Rule of Evidence 402, which provides that "[i]rrelevant evidence is not admissible," and Federal Rule of Evidence 403, which provides that relevant evidence may be excluded "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, [or] wasting time."

Trial began in the Southern District of Florida on November 3, 2014, and continued over eight days. The plaintiffs offered twenty-five

witnesses, including themselves and their implanting physicians. The witnesses, mostly doctors, testified regarding the plaintiffs' medical conditions, implantation processes, and injuries; BSC's structure and policies; the Pinnacle's development process; and the Pinnacle's and polypropylene mesh's chemical characteristics, design features, uses, and potential dangers. BSC contested all four of the plaintiffs' claims on the merits and also asserted Florida's four-year statute of limitations for products liability claims as an affirmative defense against Eghnayem's claims in particular. At the conclusion of the plaintiffs' case, and again after the conclusion of their own case, BSC moved for judgment as a matter of law on all claims; the district court deferred ruling. The jury returned a verdict in favor of each of the plaintiffs on all claims except for punitive damages, and rejected BSC's statute of limitations defense, awarding $6,722,222 in damages to Eghnayem, $6,533,333 to Nuñez, $6,766,666 to Dotres, and $6,722,222 to Betancourt.

BSC renewed its motion for judgment as a matter of law on all of the plaintiffs' claims. BSC argued, among other things, that Eghnayem failed to present sufficient evidence on her design defect claim; that the

Pinnacle's warnings were adequate as a matter of law, and that regardless Eghnayem failed to show that the alleged failure to warn was the proximate cause of her injuries; and, finally, that the evidence indisputably showed that Eghnayem's claims had accrued more than four years before she filed suit. The district court rejected all of these arguments, concluding that Eghnayem had provided sufficient evidence to support her claims and thus they were all properly reserved for the jury.

BSC also moved in the alternative for a new trial on the grounds that it was substantially prejudiced by the wrongful exclusion of the 510(k) evidence, and that consolidation confused the jury and also prejudiced BSC. Again, the district court rejected these arguments, based largely on the same reasoning it had provided in the initial consolidation and exclusion orders.

BSC now appeals the denial of these post-trial motions.

## II.

We review a district court's decision whether to consolidate multiple actions only for a "clear abuse of discretion." Hendrix v. Raybestos-Manhattan, Inc., 776 F.2d 1492, 1495 (11th Cir. 1985). We

also review the evidentiary rulings of a trial court "only for a clear abuse of discretion." United States v. Brannan, 562 F.3d 1300, 1306 (11th Cir. 2009). "[W]e must affirm unless we find that the district court has made a clear error of judgment, or has applied the wrong legal standard." Id. (quoting United States v. Frazier, 387 F.3d 1244, 1259 (11th Cir. 2004) (en banc)). Finally, we review the district court's ruling on a motion for judgment as a matter of law de novo, considering the evidence and the reasonable inferences drawn from it in the light most favorable to the nonmoving party. Middlebrooks v. Hillcrest Foods, Inc., 256 F.3d 1241, 1246 (11th Cir. 2001). Thus, we've explained, "[j]udgment as a matter of law is appropriate only if the evidence is so overwhelmingly in favor of the moving party that a reasonable jury could not arrive at a contrary verdict." Id.

**III.**

BSC first contends that the district court abused its discretion by consolidating the plaintiffs' suits, because individual issues predominated and the consolidation yielded unacceptable prejudice. BSC also argues that the district court abused its discretion by excluding evidence relating to the Pinnacle's clearance through the

FDA's 510(k) regulatory process, because this evidence was relevant to the Pinnacle's safety. Neither claim succeeds.

**A.**

The district court acted well within its discretion in consolidating each of these four lawsuits. Under Federal Rule of Civil Procedure 42(a), a district court may consolidate multiple actions that "involve a common question of law or fact." A district court's decision whether to consolidate is "purely discretionary." Hendrix, 776 F.2d at 1495. In exercising its considerable discretion, the trial court is obliged to consider:

> Whether the specific risks of prejudice and possible confusion are overborne by the risk of inconsistent adjudications of common factual and legal issues, the burden on parties, witnesses and available judicial resources posed by multiple lawsuits, the length of time required to conclude multiple suits as against a single one, and the relative expense to all concerned of the single-trial, multiple-trial alternatives.

Id. (quotation omitted and alterations adopted). Moreover, "[t]he court must also bear in mind the extent to which the risks of prejudice and confusion that might attend a consolidated trial can be alleviated by utilizing cautionary instructions to the jury during the trial and controlling the manner in which the plaintiffs' claims (including the

defenses thereto) are submitted to the jury for deliberation." Id. "A joint trial is appropriate where there is clearly substantial overlap in the issues, facts, evidence, and witnesses required for claims against multiple defendants." Allstate Ins. Co. v. Vizcay, 826 F.3d 1326, 1333 (11th Cir. 2016) (quotation omitted and alteration adopted). But "[w]here prejudice to rights of the parties obviously results from the order of consolidation, the action of the trial judge has been held reversible error." Dupont v. S. Pac. Co., 366 F.2d 193, 196 (5th Cir. 1966).[2] "District court judges in this circuit have been urged to make good use of Rule 42(a) in order to expedite the trial and eliminate unnecessary repetition and confusion." Young v. City of Augusta, 59 F.3d 1160, 1169 (11th Cir. 1995) (quotation omitted and alterations adopted).

The district court did not abuse its discretion in concluding that the considerations surrounding consolidation weighed in favor of joining these suits for trial. The plaintiffs all brought the same claims based largely on the same facts: BSC's Pinnacle device was

[2] Former Fifth Circuit cases decided before October 1, 1981 are binding precedent in the Eleventh Circuit. See Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981).

unreasonably dangerous by design, and BSC failed to include sufficient warnings with the device to alert physicians to that danger. Although each plaintiff's proof of causation was necessarily different, generally differences in causation are not enough, standing alone, to bar consolidation of products liability claims. And any danger of prejudice arising from the consolidation was reduced in this case, because the district court explained the consolidated nature of the trial to the jury and expressly instructed it to consider each plaintiff's claims separately. Notably, this is not the first time we have affirmed the consolidation of products liability claims that require individual evidence of causation. Thus, for example, in Hendrix v. Raybestos-Manhattan, Inc., we affirmed a district court's decision to consolidate four products liability cases that all alleged that asbestos exposure caused them to contract an asbestos-related disease, notwithstanding the presentation of different bodies of proof on causation. 776 F.2d at 1495–96.

BSC nonetheless contends that consolidation was improper because the plaintiffs' evidence was presented in a confusing and disjointed manner, but this argument is largely beside the point.

Confusing or not, most of the evidence went toward the common claims among the plaintiffs: (1) whether the Pinnacle was a defective medical device and (2) whether the Pinnacle's warnings were sufficient. The only evidence that went to the individual claims came from the more-easily-distinguishable doctors who did each plaintiff's implantation, and concerned comparatively straightforward questions: (1) did the Pinnacle's design cause that plaintiff's injuries, and (2) did the lack of sufficient warnings influence that doctor's decision to implant the Pinnacle. BSC has not shown that this individual evidence made the suit so confusing that it was obviously prejudiced and thus has failed to tie the confusion to the consolidation order.

BSC also suggests that the plaintiffs' similar damages awards in the amounts of $6,766,666, $6,722,222, $6,722,222, and $6,533,333, respectively, show that the jury was confused by the consolidated suits. The district court rejected this argument too because BSC failed to point to any direct source of the jury's alleged confusion, and instead effectively "work[ed] backwards, speculating as to the reason for the compensatory awards based on the end result." The district court was correct. Nearly identical or identical damages awards, without more,

simply are not sufficient evidence of juror confusion. The plaintiffs suffered similar injuries caused by the same product, and so might reasonably be due similar relief. And notably, the awards were not all identical; the fact that two were the same and two were different strongly suggests that the jury considered each plaintiff individually. BSC fails to point us to any evidence that the jury's decision to award similar damages to each plaintiff was improper. This allegation of confusion is far from enough to show that the district court abused its discretion.

BSC also says that consolidating the four plaintiffs for trial led the jury to believe that their claims were more likely to be true, but this argument fails. For starters, the district court instructed the jury that "[y]ou may not even consider the fact that there's more than one case being brought," an instruction that the jury presumably followed. See United States v. Stone, 9 F.3d 934, 938 (11th Cir. 1993) ("Few tenets are more fundamental to our jury trial system than the presumption that juries obey the court's instructions."). And even had the cases not been consolidated, the plaintiffs would likely have been able to submit evidence of other patients with similar injuries to show the dangerous

character of the Pinnacle. See, e.g., Jones v. Otis Elevator Co., 861 F.2d 655, 661 (11th Cir. 1988) ("We have held that evidence of similar accidents might be relevant to the defendant's notice, magnitude of the danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, strength of a product, the standard of care, and causation.") (quotation omitted). Moreover, consolidation of products liability cases will always implicate this concern, and this Court has affirmed consolidation in these kinds of cases before. See, e.g., Hendrix, 776 F.2d at 1495–96.

BSC's final argument is that, due to the differences in the plaintiffs' claims, consolidation allowed evidence into trial that would have been individually inadmissible for some of the plaintiffs. This claim fails as well. As an initial matter, BSC failed to request limiting instructions for any of the challenged evidence. The failure to contemporaneously raise the issue denied the district court the chance to address the problem by issuing limiting instructions, and it deprives this Court of the benefit of the district court's decisions. See Access Now, Inc. v. Sw. Airlines Co., 385 F.3d 1324, 1331 (11th Cir. 2004) ("[A]s a court of appeals, we review claims of judicial error in the trial

courts. If we were to regularly address questions -- particularly fact-bound issues -- that [the district court] never had a chance to examine, we would not only waste our resources, but also deviate from the essential nature, purpose, and competence of an appellate court."); see also Fisher v. Ciba Specialty Chems. Corp., 245 F.R.D. 539, 543 n.7 (S.D. Ala. 2007) (noting that "appropriate limiting instructions" can be used to cabin "evidence relevant to the claims of one plaintiff but not to others"); United States v. Miranda, 197 F.3d 1357, 1360 (11th Cir. 1999) ("The failure to give a limiting instruction is error only when such an instruction is requested."). BSC's failure severely weakens its argument.

Moreover, it's far from clear that the complained-of evidence would have been excludable even if each of the plaintiffs had tried their cases alone. BSC identifies three pieces of evidence that may have been inadmissible in individual trials: graphic images and testimony regarding one plaintiff's removed mesh; information about another plaintiff's future scheduled surgery; and evidence relating to BSC's practices and the Pinnacle's safety that post-dated some but not all of the plaintiffs' implantations. As for the first, BSC generally objected to

the graphic images and testimony under Rule 403, arguing that the possibility of prejudice substantially outweighed any probative value. The court overruled that objection, and that decision was not an abuse of discretion. Graphic medical photos and testimony, while potentially disturbing, might also be particularly helpful in allowing a jury to better understand a medical device and the allegedly related injuries. See Aycock v. R.J. Reynolds Tobacco Co., 769 F.3d 1063, 1069 (11th Cir. 2014) ("[A] district court's discretion to exclude evidence under Rule 403 is narrowly circumscribed.") (quotation omitted); Gen. Elec. Co. v. Joiner, 522 U.S. 136, 141 (1997) ("[A]buse of discretion is the proper standard of review of a district court's evidentiary rulings."). In this case, the very feature that made the images graphic -- the tissue that was removed along with the mesh -- is what made them relevant to the plaintiffs' claim that the very nature of the Pinnacle's design prevented the removal of the mesh without removing tissue. BSC has not convinced us that this evidence would have been any less relevant, or any more prejudicial, in individual trials. See Hahn v. Sterling Drug, Inc., 805 F.2d 1480, 1483 (11th Cir. 1986) (noting that evidence of prior incidents that might be relevant to "the magnitude of danger,"

"the lack of safety," or "causation" "should not be excluded").

As for the second challenged piece of evidence, BSC did not object at all to the two mentions of one plaintiff's future scheduled surgery, and further has not suggested that this evidence would be excludable in individual trials under any rule of evidence except perhaps Rule 403. We fail to see how the danger of unfair prejudice from the mere mention of future surgery warrants invoking the strong medicine of Rule 403 exclusion. See United States v. Dodds, 347 F.3d 893, 897 (11th Cir. 2003) ("[W]e have [ ] recognized that Rule 403 is an extraordinary remedy which the district court should invoke sparingly, and the balance should be struck in favor of admissibility.") (quotation omitted and alteration adopted). Once again, BSC has not shown that this evidence would have been inadmissible for some of the plaintiffs individually.

Finally, as for the third challenged set of evidence, BSC fails to show that the evidence post-dating some of the implantations -- including admissions from BSC employees tending to show a pattern of insufficient research for other medical devices, and information suggesting a high erosion rate for the Pinnacle -- would not

be admissible for at least some purposes in each individual trial. A pattern of insufficient research might be probative evidence as to whether BSC designs products without due care, and the Pinnacle's high erosion rate is surely probative of whether BSC was strictly liable for a defective product. BSC is of course correct that this evidence could not have been used to show BSC's knowledge of the risks associated with the Pinnacle for those plaintiffs whose implantations predated the evidence. But when evidence is relevant for some purposes and not others, limiting instructions -- not exclusion -- are generally the best way to handle the issue. See, e.g., Fisher, 245 F.R.D. at 543 n.7. BSC's failure to request limiting instructions here dooms this argument.

Quite simply, BSC cannot establish that it was prejudiced by the consolidation of the plaintiffs' suits. The district court did not abuse its discretion in ordering the consolidation and denying BSC a new trial.

**B.**

The district court also did not abuse its discretion when it excluded BSC's 510(k) evidence. The 510(k) review process originates from the Medical Device Amendments of 1976 (MDA) to

the Federal Food, Drug, and Cosmetic Act. The MDA was enacted in order to "impose[ ] a regime of detailed federal oversight" of medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). Under the MDA, certain devices must complete a thorough premarket approval (PMA) process with the FDA before they may be marketed, including all devices that cannot "provide reasonable assurance of the[ir] safety and effectiveness" under less stringent scrutiny, and that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "present[ ] a potential unreasonable risk of illness or injury." Id. at 317; 21 U.S.C. § 360c(a)(1)(C). The PMA process requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001); 21 U.S.C. § 360e(d)(2)(A), (B).

An exemption to the PMA requirement exists for medical devices that were already on the market prior to the MDA's enactment in 1976; these devices are allowed to remain on the market until the FDA

initiates and completes PMA review for them. See 21 U.S.C. § 360e(b)(1)(A); Buckman, 531 U.S. at 345. In order to ameliorate the monopolistic consequences of this exemption, the MDA also allows other manufacturers to market devices that are shown to be "substantially equivalent" to pre-1976 devices that are exempt from the PMA requirement. Buckman, 531 U.S. at 345 (citing § 360e(b)(1)(B)). The 510(k) process is the method by which a manufacturer demonstrates substantial equivalence. Id.

Notably, the PMA and 510(k) processes have distinct requirements and different goals. PMA "is federal safety review," Riegel, 552 U.S. at 323, whereas "the 510(k) process is focused on equivalence, not safety," Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996) (quotation omitted and alteration adopted). Indeed, "devices that enter the market through § 510(k) have never been formally reviewed . . . for safety or efficacy." Riegel, 552 U.S. at 323 (quotation omitted). Rather, the 510(k) exemption is "intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976." Lohr, 518 U.S. at 494.

These differences are reflected in the intensity of review: "[I]n contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." Id. at 479; see also Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1369 n.1 (11th Cir. 1999) ("[T]he FDA completes the average 510k review within 20 hours, and the agency considers only whether the device is indeed the equivalent of a preexisting device -- regardless of how unsafe or ineffective the grandfathered device happens to be."). The two processes are "by no means comparable." Lohr, 518 U.S. at 478.

Based on the arguments properly presented in this appeal,[3] it is clear that the district court did not abuse its discretion when it concluded that the 510(k) review process is not relevant to a product's safety. As the district court explained, "[i]f 510(k) does not go to a product's safety and efficacy -- the very subjects of the plaintiffs'

[3] In its reply brief, BSC argues for the first time that because the FDA determined the Pinnacle to be substantially equivalent to a post-1976 Class II device that may have undergone formal safety review, as opposed to a pre-1976 Class III device which had not, BSC's 510(k) evidence could be relevant to the Pinnacle's safety in a way that distinguishes this case from Lohr and Riegel. Because BSC failed to raise this argument in the district court, or even on appeal prior to its reply brief, we will not consider it. See Access Now, Inc., 385 F.3d at 1331 (explaining that "an issue not raised in the district court . . . will not be considered by this [C]ourt") (quotation omitted); Lovett v. Ray, 327 F.3d 1181, 1183 (concluding that an argument raised for the first time in a reply brief is not properly before this Court).

products liability claims -- then evidence of BSC's compliance with 510(k) has no relevance to the state law claims in this case." This evidence was properly excluded under Rule 402.

BSC's arguments to the contrary do not undermine this conclusion. BSC claims that the evidence is relevant because the plaintiffs based much of their case on the theory that BSC didn't perform sufficient safety testing, and because Florida has established a rebuttable presumption that a product is not defective if it complies with applicable safety regulations. But these points simply beg the question; because 510(k) is not a safety regulation, approval under that process cannot show that BSC performed sufficient testing or complied with applicable safety regulations. BSC also argues that the district court's conclusion misapplied Lohr and Riegel because those cases dealt with 510(k)'s relevance to safety in the context of preemption of state-law claims, not evidence admissibility. But the district court simply applied the Supreme Court's reasoning from those cases to reach a related, though technically distinct, conclusion -- a basic and entirely proper form of judicial analysis.

But even if the 510(k) evidence were relevant, the district court

still did not abuse its discretion when it excluded it under Rule 403. As the district court noted, the evidence "might have provoked the parties to engage in a time-consuming mini-trial on whether BSC in fact complied with [FDA] regulations." And the apparent significance of federal regulatory schemes very well might have misled the jury into thinking that general federal regulatory compliance, not state tort liability, was the core issue. These concerns of prejudice and confusion substantially outweighed the probative value of the evidence, which -- divorced as it was from any clear showing of safety review for the Pinnacle or a substantially similar device -- was low at best. Although BSC argues that any possibility of prejudice could have been "resolved with an appropriate instruction" to the jury, that option does not come close to tipping the scale in their favor. Weighing all these considerations, the court acted within its discretion by excluding the 510(k) evidence.

We are not the only circuit court to have approved exclusion of 510(k) evidence under Rule 403. The Fourth Circuit, in In re C.R. Bard, Inc., MDL No. 2187, Pelvic Repair System Products Liability Litigation, 810 F.3d 913 (4th Cir. 2016) -- reviewing another order

excluding 510(k) evidence for a vaginal mesh device -- explained that, even "[a]ssuming without deciding that the 510(k) compliance evidence is relevant," the evidence had diminished probative value because 510(k) "operate[s] to exempt devices from rigorous safety review procedures." Id. at 920. The court held that the district court did not abuse its discretion when it concluded that the possibility of "mini-trials" on the 510(k) process -- which would have included a "battle of experts" -- presented "the very substantial dangers of misleading the jury and confusing the issues." Id. at 921–22 (quotation omitted). The Fourth Circuit explained the issue this way:

> While 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that is specific. The vast majority of courts have said so, and having been thoroughly briefed not only by the parties but by several amici, we say so again today. As such, the district court did not abuse its discretion when it determined that allowing the 510(k) evidence in on the question of design defect would be substantially more prejudicial than probative.

Id. at 922.

## IV.

Even setting aside the issues of consolidation and exclusion of the 510(k) evidence, BSC argues that the district court should have

granted it judgment as a matter of law on Eghnayem's design defect and failure to warn claims, because she didn't present enough evidence to establish debatable questions of fact and because her claims were untimely. After thoroughly reviewing this record, we are satisfied that Eghnayem provided sufficient evidence in her favor, so her claims were properly reserved for the jury. The district court did not err by declining to overturn the jury's verdict.

**A.**

The district court did not err by denying judgment as a matter of law to BSC on Eghnayem's design defect claims. We are Erie-bound in diversity cases to apply the tort law of Florida. Erie R. Co. v. Tompkins, 304 U.S. 64, 78 (1938). In Florida, "a product is defectively designed if the plaintiff proves that the design of the product proximately caused the plaintiff's injuries and the defendant fails to prove that on balance, the benefits of the design outweigh the risk of danger inherent in the design." Force v. Ford Motor Co., 879 So. 2d 103, 106 (Fla. Dist. Ct. App. 2004). This test, known as the "risk-utility" test, is one of two ways to show that a design is defective under the strict products liability standard laid out in the Second Restatement

of Torts. Jennings v. BIC Corp., 181 F.3d 1250, 1255 (11th Cir. 1999). We have acknowledged that Florida has adopted this standard. Id. (citing West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976)). In this case, the jury was instructed on only the risk-utility test.

Eghnayem presented expert testimony of two specific defects in the Pinnacle: the polypropylene material may experience oxidative degradation, which causes it to lose its physical and mechanical properties in a way that causes injury; and the crosshatched design of the mesh makes it very difficult, if not impossible, to remove if there is a problem with the mesh.

Regarding polypropylene degradation, Eghnayem presented expert testimony from Dr. Mays (qualified as an expert in the field of polymer science) that polypropylene reacts with oxygen, and "[w]hen that oxidative process progresses enough, the material erodes away." When this happens, the polypropylene "stiffen[s]" and "lose[s] [its] mechanical properties," which "is relevant to the proper or improper use of polypropylene in a medical device." Mays further explained that "if you increase the surface area of the material, . . . [y]ou're going to increase the rate at which that material undergoes degradation," and

that for polypropylene fibers -- a category that the Pinnacle falls into -- "physical properties deteriorate more rapidly upon oxidation." Finally, Mays noted that degradation occurs in the body "much more readily than it does in many other environments," and once it occurs the material "can no longer move with the body." Mays testified that there is evidence that polypropylene degrades "when implanted in the female pelvis," and that such degradation may result in stiffness and ultimately "a sawing effect" that Mays believed "caus[ed] some of the problems with the mesh." Another expert, Dr. Walmsley (qualified as an expert in the field of urology), testified that when treating pelvic organ prolapse with polypropylene mesh, there are "mesh-specific risks" of pelvic pain, erosion, painful activity, and permanent tissue damage, along with a significant risk of subsequent surgery as compared to other prolapse surgical repairs -- approximately a "threefold" increase.

As for the difficulty surrounding the removal of the polypropylene mesh, Dr. Margolis (qualified as an expert in the fields of obstetrics and gynecology) opined that the implantation of the mesh, which has a "crosshatched" or "window screen[ ]" pattern of holes, was "irreversible" because "[s]car tissue, what are called fibroblasts, scar

cells, move into the [holes in the] mesh and they cement the mesh into place." Margolis explained that this aspect of the mesh implantation makes it very difficult to treat mesh injuries, complications, and erosions.

When taken in concert, this expert testimony provided a sufficient foundation for a reasonable jury to conclude that the design of the mesh increased both the potential for degradation and the difficulty of removal. The ultimate question whether these risks outweighed the Pinnacle's benefits was for a jury to decide. The district court correctly did not second-guess the jury's verdict.

BSC's arguments to the contrary are unavailing. BSC claims that the "purported design defect is a matter not of kind (like the presence of polypropylene) but of degree (the surface area of polypropylene)," and thus that Eghnayem was required to establish "the minimum threshold beyond which the product is defective." But this argument is a red herring. This type of analysis is used in toxic tort cases, where some exposure to a toxic substance may be acceptable, but past a certain threshold exposure becomes harmful. See, e.g., McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241 (11th Cir. 2005) ("In toxic tort cases,

scientific knowledge of the harmful level of exposure to a chemical plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff's burden.") (quotation omitted and alteration adopted). But in this case, there is no question of threshold; the Pinnacle was either harmful or not.

BSC also argues that Eghnayem's implanting physician testified that polypropylene was safe and effective, and that this somehow defeats her claim of a design defect. But any testimony from her experts that tended to weaken her design defect claim is irrelevant to judgment as a matter of law; the weighing of conflicting evidence is properly for the jury. See Pensacola Motor Sales Inc. v. E. Shore Toyota, LLC, 684 F.3d 1211, 1226 (11th Cir. 2012) (explaining that, in reviewing the denial of a motion for judgment as a matter of law, "we must disregard all evidence favorable to the moving party that the jury is not required to believe") (quotation omitted).

Taking the evidence in the light most favorable to Eghnayem, there was sufficient evidence for a reasonable jury to find that the Pinnacle had a design defect. Accordingly, the district court correctly denied BSC's motion for judgment as a matter of law.

**B.**

The district court did not err by denying judgment as a matter of law to BSC on Eghnayem's failure to warn claims either. Under Florida law, to succeed on a failure to warn claim a plaintiff must show (1) that the product warning was inadequate; (2) that the inadequacy proximately caused her injury; and (3) that she in fact suffered an injury from using the product. Hoffmann-La Roche Inc. v. Mason, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009). For medical products like the Pinnacle, "the duty to warn is directed to physicians rather than patients under the 'learned intermediary' doctrine." Id. This is so because the prescribing physician acts as an intermediary between the manufacturer and the consumer, weighing the potential benefits of a device against the dangers in deciding whether to recommend it to meet the patient's needs. Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989). Consequently, to satisfy the causation element, a plaintiff must show that her treating physician would not have used the product had adequate warnings been provided. See id. at 105 (explaining that "the drug manufacturer could not be penalized for the failure of the doctor to impart knowledge concerning the dangers of the drug of which the

doctor had been warned and was aware").

"While in many instances the adequacy of warnings . . . is a question of fact," the Florida Supreme Court has held that "it can become a question of law where the warning is accurate, clear, and unambiguous." Felix, 540 So. 2d at 105. "[T]he adequacy or inadequacy of the warning to inform a physician must, except in the more obvious situations, be proved by expert testimony." Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990). "To warn adequately, the [warning] label must make apparent the potential harmful consequences." Farias v. Mr. Heater, Inc., 684 F.3d 1231, 1233 (11th Cir. 2012) (quoting Scheman-Gonzalez v. Saber Mfg. Co., 816 So. 2d 1133, 1139 (Fla. Dist. Ct. App. 2002)). Generally, "[t]he warning must be of such intensity as to cause a reasonable man to exercise for his own safety caution commensurate with the potential danger." Id. (quoting Scheman-Gonzalez, 816 So. 2d at 1139). But "[w]hen a warning is designed to inform a 'learned intermediary,' it is somewhat easier to establish the adequacy of the warning because it will be read and considered by a trained expert." Hayes v. Spartan Chem. Co., 622 So. 2d 1352, 1354 (Fla. Dist. Ct. App. 1993).

The Florida Supreme Court has ruled at least twice in notable cases that warnings were adequate as a matter of law. In Felix, the court considered a label warning that explained "[b]ecause teratogenicity has been observed in animals given [the drug], patients who are pregnant or intend to become pregnant" should not use it, and female patients "should be fully counseled on the potential risks to the fetus should they become pregnant while undergoing treatment." Felix, 540 So. 2d at 103. The court noted that the prescribing doctor testified that he understood the warnings, and ultimately ruled that these warnings were adequate as a matter of law to alert physicians to the possible risk of birth defects from the drug. Id. at 105. In Upjohn, the Florida Supreme Court considered a warning that mentioned the following potential adverse reactions: breakthrough bleeding, spotting, and change in menstrual flow. Upjohn, 562 So. 2d at 682. The court observed that "no medical expert testified that the package insert was insufficient to put a doctor on notice" that the medication could cause the plaintiff's "excessive and continuous menstrual bleeding," and concluded that, as "the insert warned of the possibility of abnormal bleeding outside of the menstrual period," "[i]t would be unreasonable

to hold Upjohn liable for not characterizing the bleeding as excessive, continuous, or prolonged." Id. at 683.

At trial Eghnayem argued that BSC failed to warn doctors that, in the event of a problem with the Pinnacle, it could be difficult or even impossible to remove. The Pinnacle's directions for use contained the following warnings:

> Hysterectomy may be needed in the future; Use of mesh may make future hysterectomies more difficult due to tissue in-growth and scarring.
>
> In the event that infection presents post procedure, the entire mesh many have to be removed or revised.
>
> Tissue responses to the implant could include local irritation at the wound site, vaginal erosion or exposure through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction, and inflammation. The occurrence of these responses may require removal or revision of the mesh.

Eghnayem offered expert testimony from Dr. Margolis that these warnings failed to inform doctors that "a patient may need multiple operative procedures to remove the mesh"; that "when you remove portions of the mesh, part of the normal tissue has to come out with it," so that "you can[not] just take the mesh out and everything is fine"; and that mesh implantation ultimately may be "irreversible."

Eghnayem carried her burden here. While the Pinnacle's warnings may have been sufficient to notify doctors that multiple procedures might be needed to remove the mesh, the warnings do not even remotely suggest that removal might be impossible. Indeed, the repeated warnings that removal might be necessary suggest just the opposite. And the warnings also failed to notify doctors that removal of the mesh might require removal of healthy tissue as well. The closest they come is by warning that "future hysterectomies [may be] more difficult due to tissue in-growth and scarring," but that warning is not so unambiguous that it would be unreasonable for a jury to hold BSC liable for failure to warn.

BSC argues, nevertheless, that the Pinnacle's warnings were sufficiently clear that they merited judgment as a matter of law under Upjohn. But the district court was correct to conclude that "the difference between Upjohn and the case at bar is one of degree -- the injuries experienced by the plaintiff in Upjohn were a minor departure from the risks warned of in the package insert, but the same cannot be said here." Because the Pinnacle warnings did not explain that the complications they warned of could be "permanent, irreversible, and

untreatable," the departure was not so minor that the entry of judgment as a matter of law was warranted.

Eghnayem also proffered sufficient evidence that BSC's failure to warn caused her injuries. BSC argues that she failed to show that the inadequate warnings affected her doctor's decision to use the Pinnacle, but her doctor testified that he would have liked to know the risk of mesh contracture, acute and permanent inflammation, and chronic pain, and that had he known he would have had "concerns about [ ] using [the Pinnacle] in a patient" and would have discussed those concerns with Eghnayem. This testimony does not "point so overwhelmingly in favor of" BSC that no reasonable jury could find that the failure to warn proximately caused Eghnayem's injuries. Slicker v. Jackson, 215 F.3d 1225, 1229 (11th Cir. 2000) (quotation omitted).

**C.**

Finally, the district court did not err by denying judgment as a matter of law to BSC on its argument that Eghnayem's claims were time barred. It was not unreasonable for the jury to find that Eghnayem's claims accrued after April 11, 2009 -- the cut-off point for the state's four-year statute of limitations.

Under Florida law, plaintiffs have four years to bring a products liability action. Fla. Stat. §§ 95.11(3)(e), 95.031. Accrual for these actions is governed by the discovery rule, according to which the statute of limitations period does not begin to run until "the date that the facts giving rise to the cause of action were discovered, or should have been discovered with the exercise of due diligence." Id. § 95.031(2)(b). The Florida Supreme Court has explained that the knowledge required to commence the running of the limitations period under the discovery rule need "not rise to that of legal certainty." Univ. of Miami v. Bogorff, 583 So. 2d 1000, 1004 (Fla. 1991), holding modified on other grounds by Tanner v. Hartog, 618 So. 2d 177 (Fla. 1993). Rather, "[p]laintiffs need only have notice, through the exercise of reasonable diligence, of the possible invasion of their legal rights." Id. Notice, in turn, "ha[s] two essential ingredients: an injury distinct in some way from conditions naturally to be expected from the plaintiff's condition, and . . . exposure to the product in question." Babush v. Am. Home Prods. Corp., 589 So. 2d 1379, 1381 (Fla. Dist. Ct. App. 1991) (emphasis omitted). "Use of the conjunction 'and' in this equation necessarily implies that the connection must be to some extent causal."

Id.

Florida precedent sheds considerable light on what it takes for an injury to meet this notice standard. In Bogorff, the Florida Supreme Court concluded that a three-year-old's symptoms of slurred speech, impaired motor skills, convulsions, coma, and resultant paralysis and brain damage, which coincided in time with the introduction of a particular leukemia medication, were sufficiently dramatic to provide notice to his parents. 583 So. 2d at 1001, 1004. In Norsworthy v. Holmes Reg'l Med. Ctr., Inc., on the other hand, a Florida appellate court held -- in the highly analogous medical malpractice context -- that a child's difficulty breathing following an invasive medical procedure was not so obviously unusual that it put his parents on notice of their malpractice claim. 598 So. 2d 105, 108 (Fla. Dist. Ct. App. 1992). The court explained that when "there is nothing about an injury that would communicate to a reasonable lay person that the injury is more likely a result of some failure of medical care than a natural occurrence that can arise in the absence of medical negligence, the knowledge of the injury itself does not necessarily trigger the running of the statute of limitations." Id. at 107. Because even "medical treatment competently

performed" might cause new unpleasant symptoms, an injury must stand out from the norm to start the statutory clock. Id. at 108.

Thus, to merit judgment as a matter of law for BSC, the evidence must have been clear that Eghnayem was aware of a "dramatic change in [her] condition," and further that she knew of the possible involvement of the Pinnacle in that change, by April 11, 2009 -- four years before she filed suit. See Bogorff, 583 So. 2d at 1004; Middlebrooks, 256 F.3d at 1246. The evidence was not that clear. While Eghnayem did exhibit one new symptom in 2008 -- urinary incontinence -- that could have been associated with a defect in the Pinnacle, that symptom was not so obviously unusual as to indisputably put Eghnayem on notice about her claim. Incontinence is a more dramatic symptom than some, but judgment as a matter of law is a high standard, and it was not "patently clear" or "obvious" that Eghnayem's incontinence was a sufficiently distinct symptom from what might be expected after vaginal surgery to put her on notice of her cause of action against BSC. See United States v. Groessel, 440 F.2d 602, 606 (5th Cir. 1971).

BSC argues that Eghnayem's testimony that, after consulting

with her doctor in October 2008, she believed this new symptom "w[as] related to the mesh repair" showed she was on notice at that time. But "mesh repair" could refer to the implantation surgery, along with any complications, as opposed to the Pinnacle device itself. BSC's protestation to the contrary -- that "[n]o rational juror could conclude that Eghnayem testified the implant surgery, rather than the mesh itself, was 'related' to her 'problems'" because "[s]he never blamed her surgeon, and she presented no evidence that her 'problems' were caused by surgical technique" -- misses the point. The question is not whether a reasonable jury could conclude that her injuries were caused by the surgery, but rather whether the jury could conclude that Eghnayem reasonably believed that her incontinence was a result of the surgery instead of the Pinnacle. Ultimately, a jury could have reasonably concluded that Eghnayem's injury was not so "distinct . . . from conditions naturally to be expected from [her post-surgical] condition," and so the timeliness of Eghnayem's action was properly a question of fact for the jury. Babush, 589 So. 2d at 1381.

The long and short of it is that the district court properly

exercised its broad discretion in consolidating these actions and refusing to admit FDA evidence, and the contested fact questions were properly presented to the jury.

**AFFIRMED.**